

COVID-19 Vaccine –Operation Readiness

November 24, 2020



DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

November 23, 2020

Discussion Topics

- Opening Remarks
- Vaccine Updates
- Provider Enrollment
- Expert Vaccine Allocation Panel
- Q&A

Vaccine Updates

COVID-19 Vaccine Landscape

Manufacturer	Platform	Age Group	needed ²	Timing	Storage/Handling		
Moderna ¹	mRNA	≥18 years	2	0, 28 days	Frozen 30 days refrigerated		
Pfizer/BioNTech ¹	mRNA	≥ 12 years	2	0, 21 days	Ultra Cold Frozen 5 days refrigerated		
AstraZeneca/Oxford	Non-replicating Viral Vector	≥18 years	2	0, 28 days	Refrigerated		
Janssen/Johnson & Johnson ¹	Non-replicating Viral Vector	≥18 years	1	N/A	Frozen 3 months refrigerated		
Novavax	Recombinant Protein Subunit	<u>></u> 18 years	2	0, 21 days	Refrigerated		
Sanofi/GSK	Recombinant Protein Subunit	TBD	2	TBD	Refrigerated		
1. Phase 3 2: Intramuscular injection							



COVID-19 Vaccine Updates AstraZeneca Candidate

- AstraZeneca is the third company to announce the positive interim analysis of their Phase 3 trial of COVID-19 vaccine candidate (AZD1222) in the **UK and Brazil**.
- The interim analysis is based on 131 COVID-19 cases.
- Two different dosing regimens demonstrated efficacy with one showing a better profile
 - One dosing regimen (n=2,741) showed vaccine efficacy of 90% when AZD1222 was given as a half dose, followed by a full dose at least one month apart.
 - Another dosing regimen (n=8,895) showed 62% efficacy when given as two full doses at least one month apart.
 - The combined analysis from both dosing regimens (n=11,636) resulted in an average efficacy of 70% (p \leq 0.0001).
 - Half dose (~2.5 x10¹⁰ viral particles) or full dose (~5x10¹⁰ viral particles) of AZD1222.
 - No hospitalizations or severe cases of COVID-19 in participants treated with AZD122.
- The US Phase 3 study is still ongoing.



COVID-19 Vaccine Updates Regulatory Updates

- The FDA has confirmed the date for its advisory committee (VRBPAC-Vaccine Related Biological Products Committee) on December 10th.
 - This will be a publicly-held meeting.
- VRBPAC will provide a recommendation to the FDA on whether or not to authorize the vaccine for emergency use, with the FDA making the final decision.
- Upon the issuance of an EUA for a vaccine by the FDA, the Advisory Committee on Immunization Practices (ACIP) will quickly hold a public meeting to review all available data about the vaccine.
- ACIP will vote on whether to recommend the vaccine, and if so, who should receive it and who should receive COVID-19 vaccines if supply is limited.



Provider Enrollment

COVID-19 Enrolled Vaccine Providers by County Counties with at least Tenne Oklahoma one provider Arkansas 221 New Mexico Mississippi 2/3 Alabam 4/5N 9/10 Louisiana Number of Providers 6/55 Sonora 8 1-10 **Enrolled Providers By Region** 10-50 **Enrolled Providers Enrolled Providers** 50-100 **Public Health Region** Not in ImmTrac2 In ImmTrac2 Total Coahuila de 100-200 116 31 147 Zaragoza 2/3 558 284 842 200-300 4/5N 157 38 195 >300 6/5S 716 251 967 Nuevo León 349 107 456 307 85 392 9/10 188 66 254 11 369 54 423 2,760 3,676 916 Texas

Counties with No Providers

Public Health Region									
1	2/3	4/5N	8	9/10	11				
BRISCOE	COTTLE	FRANKLIN	EDWARDS	BORDEN	JIM HOGG				
COCHRAN	HASKELL	RAINS	GOLIAD	COKE	KENEDY				
DICKENS	KENT	RED RIVER	REAL	DAWSON	LIVE OAK				
HARTLEY	STEPHENS			GLASSCOCK	MCMULLEN				
KING				HUDSPETH					
LIPSCOMB				IRION					
MOTLEY				MARTIN					
OLDHAM				REAGAN					
ROBERTS				STERLING					
SHERMAN									



Local and Regional Microplanning

- Ensure all your local public health clinics are enrolled as providers
- Engage hospitals in your community to ensure they are ready to receive vaccine in December and know how they intend to engage beyond the hospital walls
- Identify counties or areas with no providers
- Use local knowledge to increase vaccine providers
 - Those that are active in ASN or TVFC, pharmacies, FQHCs and RHCs, especially those medical offices that see adults and reach out in areas with gaps
 - Areas with no providers, or adjacent areas that may have more potential providers



Texas Department of State

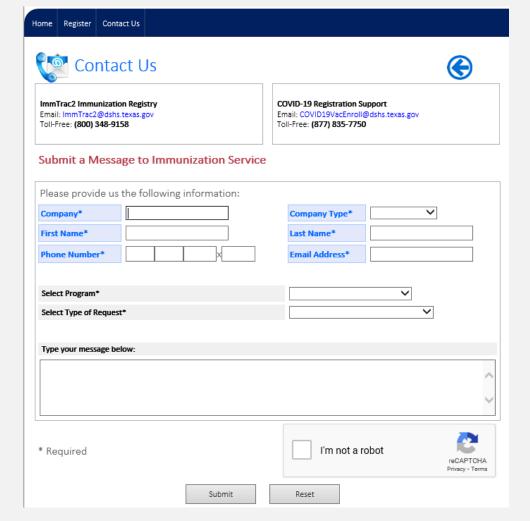


TEXAS
Health and Human
Services

Texas Department of State Health Services

https://enrolltexasiz.dshs.texas.gov/emrlogin.asp

Pandemic Provider Registration Contact Us





The following items are collected during the registration process:

- Organization information
- Primary and Secondary site contact
- Fridge/Freezer/Ultra-Cold Storage capability
- Prescribing Providers
- Patient population



Texas Department of State Health Services



PANDEMIC PROVIDER ENROLLMENT

Enroll to request COVID-19 Vaccine

In order to receive COVID-19 vaccine, you must enroll with Texas DSHS

You will need to provide the following information to complete enrollment.

- · Confirm location and shipping address
- . Provide days and times of the week when shipments of vaccine can be received.
- PLEASE NOTE: You MUST HAVE at least one (1) day other than a Monday, which has a four (4) hour designated window for delivery of your vaccine shipment. For example: Thursday 8am to 12pm.

Proof of Vaccine Storage Capacity (On site refrigeration and freezer appliances)

Information needed for each appliance:

- · Storage Unit Location (within the facility)
- · Brand and Model
- · Storage Capacity (cubic feet)
- . Use [Primary, Backup/Overflow, Day Use]
- Refrigerator Type [Under the counter (freezerless), Standalone (freezerless), Combination (Single Control), Combination (Dual Control), Other]
- · Refrigerator Grade [Household, Commercial, Medical/Laboratory/Pharmaceutical]
- · Freezer Type [Standalone Upright, Standalone Chest, Combination (Single Control), Combination (Dual Control), Other]
- · Freezer Grade [Household, Commercial, Medical/Laboratory/Pharmaceutical]

Needed Data Logger Information (for refrigerators, freezer and backup freezer data logger)

- Data Logger Type [Built-In, Digital Data Logger (WIFI), Digital Data Logger (Wired), Other]
- Brand and Model
- Serial Number
- Calibration Expiration Date [Proof for each Data Logger of a calibration certificate not expiring within 60 days of submitting
 your enrollment request.]

Vaccine Administering Capacity

 This is the number of medical practitioners currently licensed in the state of Texas working in the facility who have Prescribing Authority.

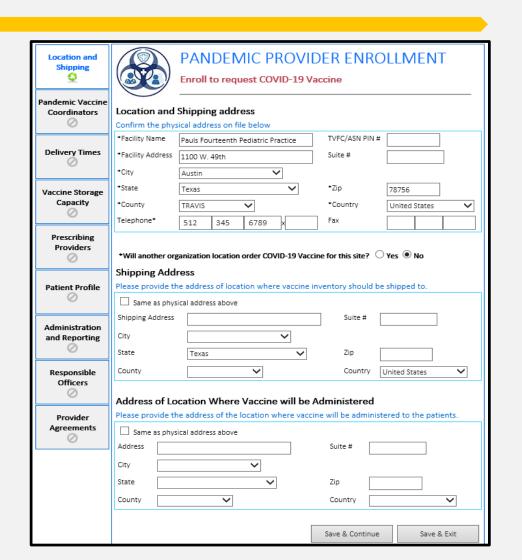
Patient Profile

. Information pertaining to the current patients served in the facility. (ex. Children, Adults and high-risk categories.)

- Organization Name (less than 40 characters in length)
- Organization's Physical and Mailing Address
- Organization's Phone Number (main phone number)
- Organization's fax number

Tip: No special characters in name or mailing address

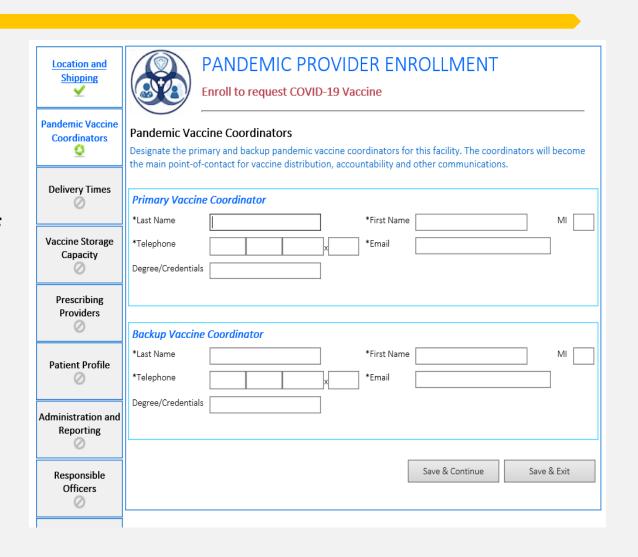




- Your Contact
 Information: First and last name, phone number, and a unique email address
- Organization's Point of Contact: First and last name, phone number, and unique email address

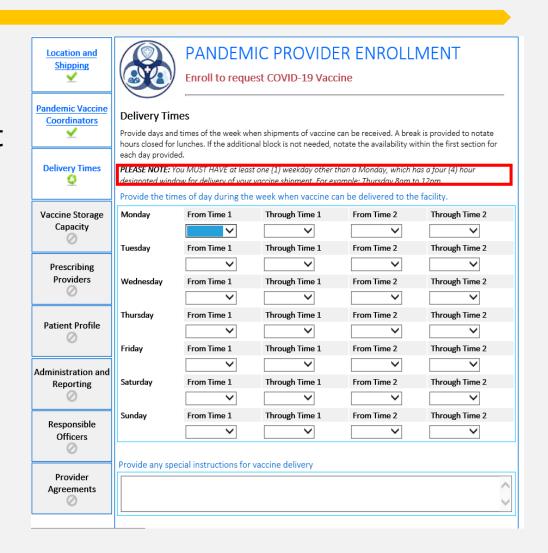
Tip: email addresses must not exceed 40 characters





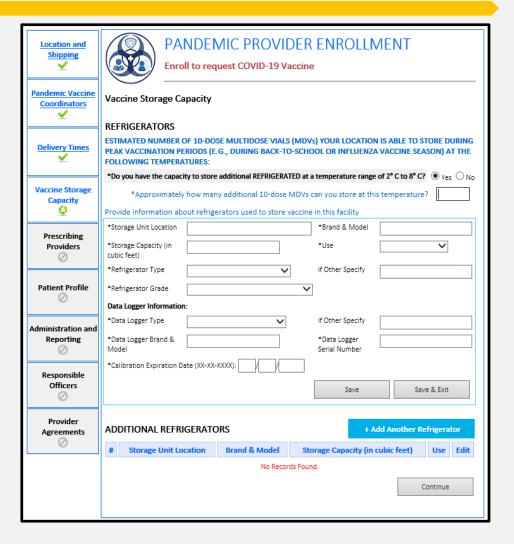
TIP: You must have at least one weekday, other than Monday, which has a four-hour designated window for delivery of vaccine shipment (for example: Friday 8 a.m. – 12 p.m.)



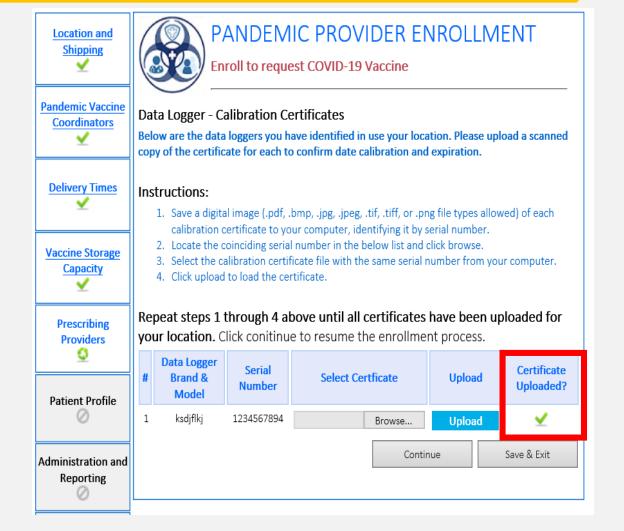


Tip: Dorm style units are never allowed





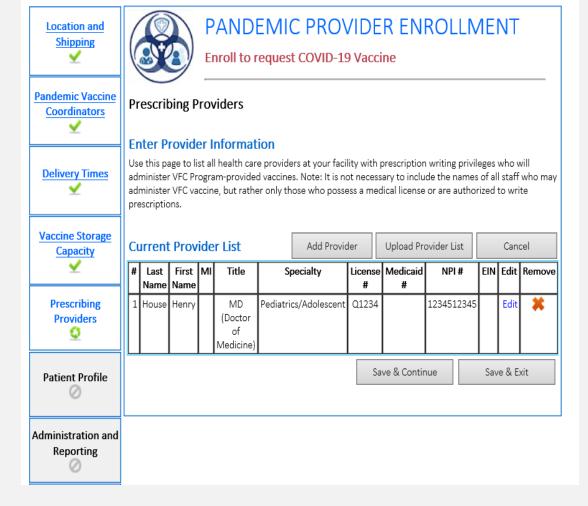
Tip: Obtain and upload the current certification of calibration for each data logger on hand.





- First and last name
- Phone number
- Unique email address
- Texas medical license number
- License type
- Individual National Provider Identification Number (NPI)
- Medicaid ID

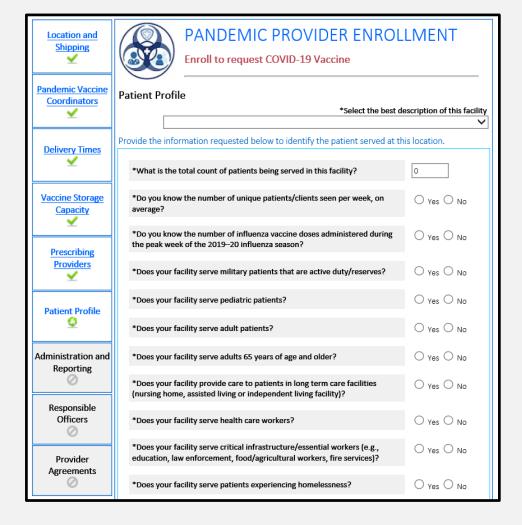
Tip: email addresses must not exceed 40 characters





Patient Population

 Provide the unique number of patients served at the organization location within the last calendar year.



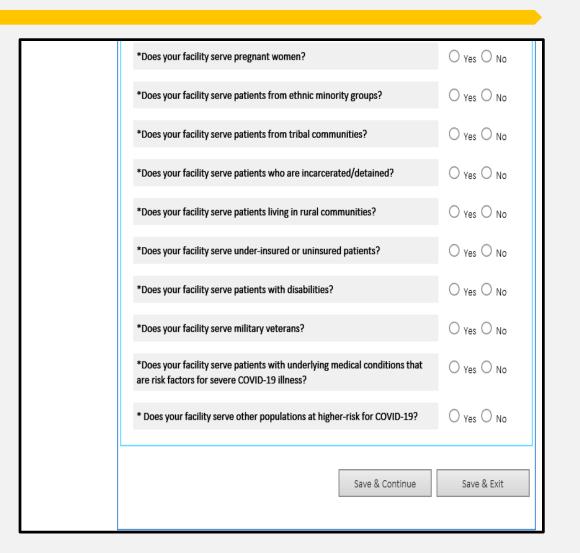


 Each category marked "Yes" in the enrollment must include the number of unique patients served, regardless of number of visits or encounters.

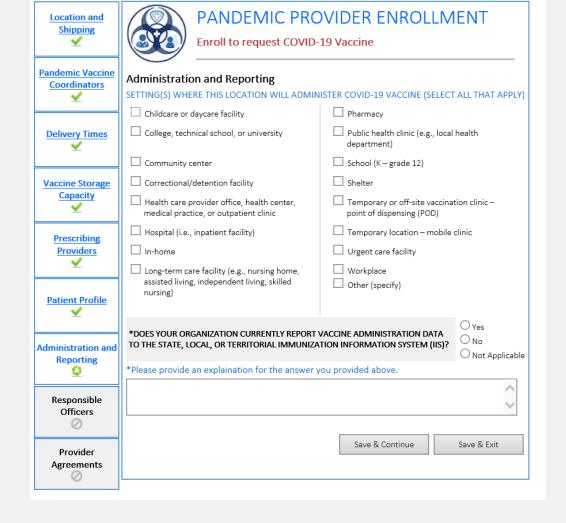
Tip: Patient profile data will determine the number of allocated COVID-19 vaccine doses to your facility.



Health Services

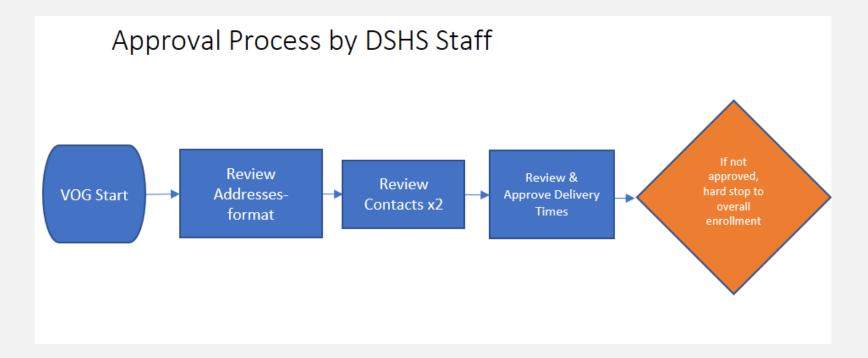


Tip: At least one category in "setting(s) where this location will administer COVID-19 vaccine" must be selected

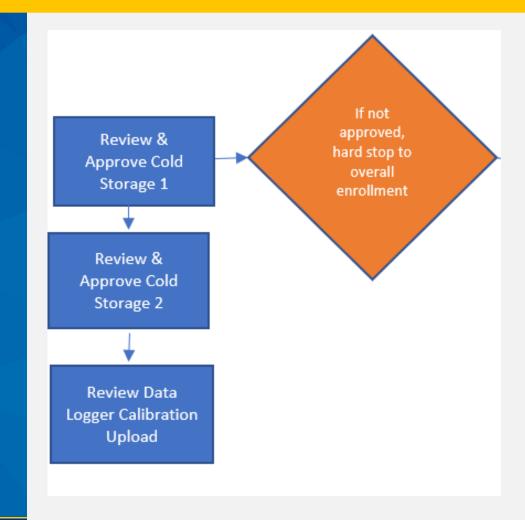




Hard stops are areas where the enrollment application cannot be approved due to CDC requirements (i.e. delivery times)



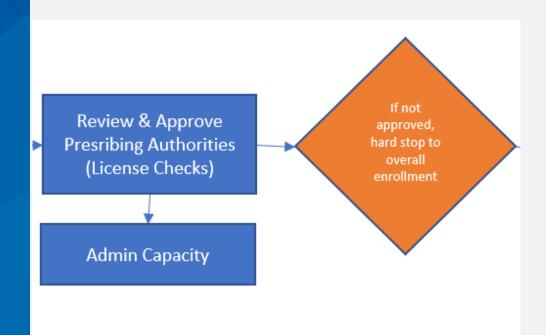




COVID-19 providers record the make and model of the storage units they have on site.

- No dorm style units are allowed
- Fridge/Freezer cubic feet/storage capacity
- Data Logger information
 - manufacturer
 - date of expiration
 - date of calibration





DSHS will review all prescribing authorities licenses.

- License status (approved, suspended, rejected, etc.)
- NPI review



Note: A provider site can have anywhere from 1 to an unknown number of licensed personnel per location, all of which will be scrutinized in the same fashion.

Each enrollment will be checked for

- Patient population numbers
- Proper signatures





Expert Vaccine Allocation Panel (EVAP)

COVID-19 Expert Vaccination Allocation Panel (EVAP)

- Texas has convened a team of appointed external and internal subject-matter experts (SME) into the COVID-19 Expert Vaccine Allocation Panel (EVAP) to develop vaccine allocation strategies as recommendations to the Texas Commissioner of Health.
- The panel will develop and apply guiding principles in their recommendations.
- The recommendations from the EVAP will be sent to the Texas Commissioner of Health for final approval.
- EVAP voting members
 https://www.dshs.texas.gov/coronavirus/immunize/evap.aspx



Texas Guiding Principles

- **Protecting health care workers** who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the health care infrastructure for all who need it.
- Protecting front-line workers who are at greater risk of contracting COVID-19 due to the nature of their work providing critical services and preserving the economy.
- Protecting vulnerable populations who are at greater risk of severe disease and death if they
 contract COVID-19.
- **Mitigating heath inequities** due to factors such as demographics, poverty, insurance status and geography.
- **Data-driven allocations** using the best available scientific evidence and epidemiology at the time, allowing for flexibility for local conditions.
- **Geographic diversity** through a balanced approach that considers access in urban and rural communities and in affected ZIP codes.
- Transparency through sharing allocations with the public and seeking public feedback.



Texas Department of State Health Services

https://gov.texas.gov/news/post/governor-abbott-dshs-announce-covid-19-vaccine-distribution-plan

COVID-19 Critical Population UpdatePhase 1A Healthcare Workers Definition – First Tier

- 1. Hospital staff working directly with patients who are positive or at high risk for COVID-19. Includes:
 - a. Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.)
 - b. Additional clinical staff providing supporting laboratory, pharmacy, diagnostic and/or rehabilitation services
- 2. Long-term care staff working directly with vulnerable residents. Includes:
 - a. Direct care providers at nursing homes, assisted living facilities, and state supported living centers
 - b. Physicians, nurses, personal care assistants, custodial, food service staff
- EMS providers who engage in 9-1-1 emergency services like pre-hospital care and transport
- 4. Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients



COVID-19 Critical Population UpdatePhase 1A Healthcare Workers Definition – Second Tier

- 1. Staff in outpatient care offices who interact with symptomatic patients. Includes:
 - a. Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.).
 - b. Clinical staff providing diagnostic, laboratory, and/or rehabilitation services
 - c. Non-91-1 transportation for routine care
- 2. Direct care staff in freestanding emergency medical care facilities and urgent care clinics.
- Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individuals who may have COVID.
- Public health and emergency response staff directly involved in administration of COVID testing and vaccinations.
- 5. Last responders who provide mortuary or death services to decedents with COVID-19. Includes:
 - Embalmers and funeral home workers who have direct contact with decedents.
 - Medical examiners and other medical certifiers who have direct contact with decedents.
- 6. School nurses who provide health care to students and teachers.



Q&A

Resources

Slides/Recordings from Weekly Forums

https://www.dshs.texas.gov/immunize/covid19/Public-Health-Entity-Forums/

Website for Providers:

www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx

FAQ for Providers

https://www.dshs.texas.gov/immunize/covid19/COVIDproviderfaq.pdf

DSHS COVID-19 Vaccine Provider hotline:

(877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or

Email: COVID19VacEnroll@dshs.texas.gov.

Website to enroll as a COVID-19 provider:

EnrollTexasIZ.dshs.texas.gov.

General Questions:

Email: COVIDvaccineQs@dshs.texas.gov